IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

GENUS LIFESCIENCES, INC. Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX AZAR, STEPHEN HAHN, M.D. Defendants.	)	Civil Action No. 8:20-cv-03282-PX

FEDERAL DEFENDANTS' MEMORANDUM
IN SUPPORT OF THEIR MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Regulations

INTRODUCTION

Genus Lifesciences, Inc.'s (Genus) Complaint is the company's latest effort to force Lannett Co., Inc. (Lannett) out of the market for cocaine-based anesthetic drug products. Genus has now filed lawsuits in multiple jurisdictions against the U.S. Food and Drug Administration (FDA) seeking to overturn FDA's approval of Lannett's new drug application (NDA) for its drug Numbrino, which would leave Genus as the only participant in that market.

Genus claims that Lannett made an "untrue statement of a material fact" in its NDA for Numbrino regarding the facility in which the drug would be manufactured. (Compl. at 2.) Genus alleges that FDA has not acted on this information—even though confidentiality regulations preclude FDA from publicly confirming or denying any inquiry it may have opened. Accordingly, Genus requests that the Court "[e]nter an order compelling FDA to immediately initiate proceedings to withdraw approval of Lannett's Numbrino® NDA." (Compl. at 24.) The Complaint, however, is plagued with jurisdictional and other infirmities that render judicial review inappropriate and require dismissal.

First, Genus brings this action under the Administrative Procedure Act (APA), but the APA specifically excludes from judicial review an agency action committed to its discretion by law. 5 U.S.C. § 701(a)(2). Supreme Court precedent has affirmed that an agency's decision "not to prosecute or enforce" is "a decision generally committed to any agency's absolute discretion" and thus outside judicial review. *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). No language in the relevant section of the Federal Food, Drug, and Cosmetic Act (FDCA) limits this discretion.

Second, Genus cannot claim that FDA unreasonably delayed a final agency action because FDA is not legally required to take the action that Genus requests. Genus reads 21 U.S.C. § 355(e) as giving a plaintiff the ability to spot an allegedly untrue, material statement in

a competitor's application and then have a court order FDA to "immediately initiate proceedings to withdraw approval." That is not the law.

Third, Genus lacks constitutional standing, prudential standing, and third-party standing. Simply having Lannett as a competitor is not a direct injury that provides standing. Genus alleges harm related to the safety and efficacy of Lannett's drugs, but any such harm is disconnected from the allegedly untrue statements in Lannett's NDA. Further, it is far from certain that the relief Genus will redress its alleged injuries because the redress depends on a speculative chain of events that may or may not occur. Genus also lacks prudential standing because it alleges only an economic harm to itself, which falls outside the "zone of the interests" protected by the relevant provision of the FDCA. In addition, Genus alleges harm to patients stemming from Lannett's change of facility, but a passing assertion of patient harm is far from sufficient to confer third-party standing to Genus on behalf of patients.

Finally, even if the Court were to determine it could review this type of claim, Genus would have to exhaust its administrative remedies before seeking judicial review, which it failed to do by not filing a citizen petition. This failure raises pragmatic concerns: FDA could grant such a petition and eliminate the need for judicial review. Also, without a citizen petition and FDA's response to such a petition, there is no record for the Court to review.

It is also important to understand the larger implications of Genus's tactics here. Under Genus's theory, a company can force an agency to investigate a competitor for any potential violation based on the company's perception that the agency has exercised its discretion not to act. Multiple legal hurdles prevent Genus from bringing such litigation for good reason. If such actions were allowed to proceed, it could cripple FDA's operations. Drug companies would scour their competitors' applications and attempt to force FDA to investigate every statement

that the companies could spin as "untrue." If forced to pursue every such hunch, FDA's limited resources would be diverted from protecting the public health to investigating the enforcement whims of drug companies.

For these reasons and as explained further below, this Court should dismiss Genus's Complaint.

BACKGROUND

A. Drug Review and Approval Process

Under the FDCA, a "new drug"[1] may not be introduced or delivered for introduction into interstate commerce unless it is the subject of an approved NDA. 21 U.S.C. § 355(a). In order to obtain approval, an applicant must submit an NDA that contains: "(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as [FDA] may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title [pediatric assessments]," as well as statutorily-specified patent information. 21 U.S.C. § 355(b).[2]

[1] A "new drug" is a drug that is not generally recognized as safe and effective, or that has not been marketed to a material extent and for a material time, for its intended uses. 21 U.S.C. § 321(p). There is no dispute that both Genus's and Lannett's drugs are "new drugs" as defined in the FDCA.

[2] An NDA may be what is known as a "505(b)(1)" or a "505(b)(2)" application, which are references to subsections (b)(1) and (b)(2) of 21 U.S.C. § 355. Unlike a 505(b)(1) application, a 505(b)(2) application relies on information from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. Both Genus's and Lannett's NDAs were 505(b)(2) applications.

The required contents of an NDA are set forth in FDA regulations promulgated through notice and comment rulemaking. *See* 21 C.F.R. § 314.50. Among those requirements are detailed instructions for completing the "chemistry, manufacturing, and controls" section of the NDA, which includes information describing the composition, manufacture, and specification of the drug substance (active ingredient) and the drug product (finished dosage form). *Id.* §§ 314.50(d)(1), 314.3(b) (defining "drug substance" and "drug product"). For both the drug substance and the drug product, an NDA must include the name and address of the manufacturer and a description of the manufacturing processes and controls. *Id.* § 314.50(d)(1). The NDA must also include information about the batches of drug product from which stability data was generated to support the proposed expiration date of the drug product. *Id.*

As part of the NDA review process, FDA evaluates the facilities involved in commercial manufacturing, which can include conducting inspections prior to approval.[3] FDA will approve an NDA unless it finds that any of the statutorily-specified reasons for refusing to approve the application apply, including that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d).

B. Withdrawing Approval of New Drug Applications

The FDCA provides grounds and a mechanism for withdrawing approval of an NDA. Among them, the statute provides that "[FDA] shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if [FDA] finds . . . that the application contains any untrue statement of a material fact." 21

[3] *See* FDA Compliance Program: Preapproval Inspections, available at https://www.fda.gov/media/121512/download (last visited Jan. 15, 2021).

U.S.C. § 355(e)(5). By regulation, FDA has set out the procedures attendant to a hearing to withdraw approval of an NDA. 21 C.F.R. § 314.200; 21 C.F.R. Part 12. Such a hearing is initiated by publication of a notice of opportunity for hearing in the Federal Register, which summarizes the basis for the proposed action. 21 C.F.R. § 314.200(a)(1), (2). The Commissioner of Food and Drugs may undertake a withdrawal of approval proceeding on his or her own initiative or in response to a citizen petition filed with the agency.[4] 21 C.F.R. § 12.21(a)(1), (3).

A citizen petition is a publicly-filed request for agency action; it must specify the action requested and contain a "statement of the grounds," described as a "full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position." 21 C.F.R. § 10.30(b)(3). Interested persons are provided an opportunity to comment on citizen petitions. *Id.* § 10.30(d).

A request for FDA action must first be the subject of final agency action in response to a citizen petition before it may be challenged in court. *See* Court review of final administrative action; exhaustion of administrative remedies, 21 C.F.R. § 10.45(b). With respect to a petition requesting that FDA withdraw approval of an NDA, if such petition were granted, withdrawal proceedings would be initiated by publishing a notice of opportunity for hearing in the Federal Register. 21 U.S.C. § 355(e); 21 C.F.R. Part 12. If such petition were denied, the petition, any

[4] The same statutory and administrative procedures apply to FDA's refusal to approve a new drug application in the first instance, in which case the petition that serves as the basis for initiating the proceeding is the application in question. 21 C.F.R. § 12.21(a)(2); 21 U.S.C. § 355(d).

public comments, and the response from FDA would be the focal point for any judicial review of the agency decision. *See* 21 C.F.R. § 10.30(i) (specifying the contents of the administrative record for judicial challenge to FDA citizen petition response).[5]

C. Genus's and Lannett's New Drug Applications

Both Genus and Lannett have approved NDAs for cocaine hydrochloride drug products indicated for use in the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults.[6] Genus's NDA for Goprelto was approved on December 14, 2017, and Lannett's NDA for Numbrino was approved on January 10, 2020. *Id.*

Shortly after Lannett's drug product was approved, Genus filed a lawsuit against FDA in the United States District Court for the District of Columbia, challenging Lannett's approval on several grounds. *Genus Lifesciences, Inc. v. Azar*, 1:20-cv-00211-TNM (D.D.C. Jan. 27, 2020) (*Genus I*). Lannett intervened. In *Genus I*, the court issued an order on September 15, 2020, granting summary judgment to Genus on one of its three claims, concluding that Lannett's NDA should have contained a patent certification and requesting additional briefing from the parties regarding the appropriate remedy.[7] *Id.* ECF No. 64. In response, FDA and Lannett filed motions

[5] *See also, e.g.*, FDA Response Denying Citizen Petition requesting withdrawal of approval of NDA for Savella, *available at* https://www.regulations.gov/document?D=FDA-2010-P-0050-0006 (last accessed Jan. 15, 2021).

[6] *See* Drugs@FDA: FDA-Approved Drugs, *available at* https://www.accessdata.fda.gov/scripts/cder/daf (FDA database of approved drug products; Genus and Lannett cocaine hydrochloride drug product approval letters and labeling available by searching "cocaine hydrochloride") (last accessed January 14, 2021).

[7] Although the court granted summary judgment to Genus on one of its claims, it agreed with FDA on a critical point of statutory interpretation, holding that the new chemical entity exclusivity held by Genus did not preclude approval of Lannett's pending application. *Id.* ECF No. 63. If the court had ruled otherwise, approval of Lannett's NDA would have been blocked until December 14, 2022. *See* FDA Orange Book: Approved Drugs with Therapeutic Equivalence Evaluations (listing exclusivity and certain patent protections associated with FDA-

for reconsideration, while Genus moved the court to vacate Lannett's approval. *Id.* ECF Nos. 66, 67, 70. As of the date of this filing, these pending motions have not yet been decided by the court.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(1), a court must dismiss an action if it finds subject matter jurisdiction lacking. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006). A court should grant such a motion when "the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991). Where a complaint challenges an action committed to agency discretion by law, a court lacks jurisdiction to review the action and should dismiss the complaint under Rule 12(b)(1). *Angelex, Ltd. v. United States*, 723 F.3d 500, 502 (4th Cir. 2013). Likewise, if a plaintiff lacks Article III standing, its complaint must be dismissed under Rule 12(b)(1) for lack of subject matter jurisdiction. *See Abbott v. Pastides*, 900 F.3d 160, 175 n.8 (4th Cir. 2018). In considering a Rule 12(b)(1) motion, the court "may consider evidence outside the pleadings" to help determine whether it has jurisdiction over the case before it. *Richmond*, 945 F.2d at 768; *see also Evans v. B.F. Perkins Co., a Div. of Standex Int'l Corp.*, 166 F.3d 642, 647 (4th Cir. 1999).

The plaintiff bears the burden of proving the existence of subject matter jurisdiction in federal court. *See Evans*, 166 F.3d at 647. Generally, "questions of subject matter jurisdiction must be decided 'first, because they concern the court's very power to hear the case.'" *Owens–*

---

approved drugs), *available at* https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last accessed Jan. 15, 2021).

Illinois, Inc. v. Meade, 186 F.3d 435, 442 n.4 (4th Cir. 1999) (*quoting* 2 James Wm. Moore, et al., *Moore's Federal Practice* § 12.30[1] (3d ed. 1998)).

ARGUMENT

Genus's effort to force FDA to withdraw approval of a competitor's NDA for any allegedly untrue, material statement contained within it fails because Genus cannot overcome multiple jurisdictional obstacles. First, the Court lacks subject matter jurisdiction because the APA specifically excludes this type of discretionary agency actions from judicial review. Further, Genus cannot identify an agency action that FDA was legally required to take, which is the predicate for an "unreasonable delay" claim under the APA. Even if this type of action were reviewable, the Court should still dismiss this case because Genus lacks standing. Genus has not articulated an injury sufficient to support standing, nor has it shown that its alleged injuries are redressable by the relief it seeks. Any alleged harm related to the safety and efficacy of Lannett's drug is disconnected from the truthfulness of Lannett's statements. Genus has also failed to establish third-party standing on behalf of patients. In addition, Genus's alleged harm is outside the "zone of interests" protected by the relevant statute, and thus Genus lacks prudential standing. Finally, Genus has failed to exhaust its administrative remedies. For all of these reasons, Genus's Complaint must be dismissed.

A. The Administrative Procedure Act Precludes Judicial Review

1. The Administrative Procedure Act Precludes Judicial Review of Agency Actions Committed to Agency Discretion

a. Not Initiating Proceedings to Withdraw an NDA Approval is an Unreviewable Agency Action Committed to Agency Discretion

The APA specifically excludes from judicial review an "agency action" that is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). The action that Genus complains of here—FDA's not initiating proceedings to withdraw approval of Lannett's NDA—

is exactly such an action. *See Stogsdill v. Azar*, 765 F. App'x 873, 878-79 (4th Cir. 2019) ("[A] federal agency's day-to-day monitoring of compliance and its decisions with respect to enforcement are committed to an agency's discretion and hence unreviewable under the APA."); *Sierra Club v. Larson*, 882 F.2d 128, 132 (4th Cir. 1989) ("Since we have determined that this was an agency decision not to seek enforcement of a statute, it is presumptively unreviewable under *Chaney*.").

Genus's Complaint seeks judicial review for FDA's alleged "failure . . . to initiate proceedings to withdraw approval of Lannett's Numbrino® NDA."[8] (Compl. ¶ 1.) But by not initiating such proceedings, FDA is exercising its discretion to not undertake a prosecutorial or enforcement action. Because FDA's action falls within the agency's "absolute discretion," it is not subject to judicial review under the APA. 5 U.S.C. § 701(a)(2); *Chaney*, 470 U.S. at 831.

b. Supreme Court Precedent Confirms FDA's Not Initiating Withdrawal Proceedings Is Not Reviewable Under the Administrative Procedure Act

In *Heckler v. Chaney*, the Supreme Court held that agencies have "absolute discretion" that is not reviewable under the APA, when—like here—the agency decides not to undertake an enforcement action. 470 U.S. at 831-33. The Supreme Court's discussion confirms that whether FDA decides to initiate proceedings to withdraw approval of a new drug application squarely fits within the exception to judicial review under the APA. *See* 5 U.S.C. § 701(a)(2).

[8] Federal Defendants note that Genus's requested relief—an "order compelling FDA to immediately initiate proceedings to withdraw approval of Lannett's Numbrino® NDA"—is ambiguous. It is unclear whether Genus seeks an order directing FDA to publish a notice of opportunity for hearing to start the process for withdrawing approval of Lannett's NDA or whether Genus seeks an order directing FDA to immediately withdraw the approval. *See* 21 U.S.C. § 355(e). As discussed more fully below, Genus is entitled to neither type of relief. Additionally, FDA's regulations prevent the agency from publicly disclosing whether or not it has undertaken an investigation of Lannett's application, *see* 21 C.F.R. § 20.64—a factor further supporting dismissal of Genus's Complaint.

In *Chaney*, the Supreme Court examined FDA's decision not to undertake enforcement action against drugs used in lethal injection. 470 U.S. at 823. It found these decisions were committed to agency discretion and not subject to judicial review under 5 U.S.C. § 701(a)(2). *Id.* at 837-38. In reaching that conclusion, the Supreme Court stated that "an agency's decision not to prosecute or enforce . . . is a decision generally committed to an agency's absolute discretion." *Id.* at 831.

The Supreme Court first explained that an agency's decision not to prosecute or enforce is "presumptively unreviewable" because such a decision "often involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Id.* Specifically, "the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id.*

The Supreme Court then explained that if Congress intends to cabin an agency's discretion, such that judicial review would be appropriate, then Congress must indicate its intent with specific language. *Id.* at 832-33. Without specific language from Congress, courts would lack a "meaningful standard against which to judge the agency's exercise of discretion." *Id.* at 830. As the D.C. Circuit summarized it, "Agency actions in these circumstances are unreviewable because the courts have no legal norms pursuant to which to evaluate the challenged action, and thus no concrete limitations to impose on the agency's exercise of discretion." *Sierra Club v. Jackson*, 648 F.3d 848, 855 (D.C. Cir. 2011) (internal citation and quotation marks omitted).

Turning to the sections of the FDCA at issue in *Chaney*, the Supreme Court then examined whether Congress had "indicated an intent to circumscribe agency enforcement discretion, and ha[d] provided meaningful standards for defining the limits of that discretion," such that review of the agency decision would be appropriate. *Chaney*, 470 U.S. at 834-35. In doing so, the Supreme Court looked specifically at sections of the FDCA related to injunctions, criminal sanctions, and seizure, and found that the FDCA's "enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised." *Id.* at 835. The Supreme Court ultimately concluded that "the presumption that agency decisions not to institute proceedings are unreviewable under 5 U.S.C. § 701(a)(2) is not overcome by the enforcement provisions of the FDCA." *Id.* at 837. Finally, the Supreme Court noted that, although 5 U.S.C. § 701(a)(2) is a "narrow" exception, included within that exception are "agency refusals to institute investigative or enforcement proceedings, unless Congress has indicated otherwise." *Id.* at 838.

The Supreme Court's decision in *Chaney* supports dismissal of Genus's Complaint. First, the Supreme Court considered the same section at issue here—21 U.S.C. § 355—and concluded that it did not provide "indicia of an intent to circumscribe enforcement discretion." *Id.* at 835-36. Specifically, respondents argued that Congress curbed FDA's discretion with 21 U.S.C. § 355 and § 352(f)—which are the FDCA's "substantive prohibitions of 'misbranding' and the introduction of 'new drugs' absent agency approval." *Id.* at 835-86. The Supreme Court rejected this argument wholesale: "These provisions are simply irrelevant to the agency's discretion to refuse to initiate proceedings." *Id.* at 836.

Further, the specific language of § 355(e) lacks any indicia that Congress intended to limit FDA's enforcement discretion. Rather, Congress did quite the opposite. Congress wrote a

broad statute: "The Secretary shall, *after* due notice and opportunity for hearing to the applicant, withdraw approval of an application . . . *if* the Secretary finds . . . ." 21 U.S.C. § 355(e) (emphasis added). The action that FDA "shall" take comes only *after* two specific antecedent events have occurred—"after . . . an opportunity for hearing" and "*if* the Secretary finds . . . that the application contains any untrue statement of a material fact." 21 U.S.C. § 355(e)(5). Further, whether to even publish a notice of opportunity for hearing requires an initial, non-public FDA inquiry. 21 C.F.R. § 314.200; *see also Nat. Res. Def. Council, Inc. v. FDA*, 760 F.3d 151, 160, 176 (2d Cir. 2014) (*NRDC*) (analyzing parallel language).

Critically, Congress provided no language to limit FDA's discretion with regard to these antecedent events. Congress did not explain *when* FDA is required to initiate investigations or *when* it must notice a hearing. And, as the Supreme Court noted in *Chaney*, agency decisions about whether and when to enforce involve the "complicated balancing of a number of factors," including "whether agency resources are best spent on this violation or another." 470 U.S. at 831. Further, Congress did not define what would make a statement in an application "untrue"[9] or "material" under § 355(e)(5), leaving the agency with broad discretion to interpret and apply those terms. Particularly in the face of a global pandemic, FDA must have discretion to direct its scarce resources in a manner that the agency determines best serves the public health.

Even if FDA were to preliminarily determine that a statement is "untrue" and "material," Congress still did not obligate FDA to act. The statute mandates action only "after due notice

[9] Even determining whether a particular representation is "untrue" may not be straightforward. For example, Congress did not address whether an applicant's identification of the intended manufacturing facility or facilities must be accurate at the time the application is submitted, during the pendency of review, at the time of approval, or at some or all of those times. Nor did Congress direct FDA how to proceed if an applicant's business plans change over the course of an application review, yet the manufacturing facility named in the application remains capable of production should the agency not permit a new site.

and opportunity for hearing to the applicant" and only if the agency then makes the requisite finding. 21 U.S.C. § 355(e). The statute does not obligate FDA to initiate any such hearing and provides no guidelines on when such a hearing should be held—leaving another piece of enforcement to the discretion of FDA without any "meaningful standard" for judicial review. *See Chaney*, 470 U.S. at 830.

In sum, the only "shall" clause in § 355(e)(5) comes after there has been notice, an opportunity for hearing, and a finding, all of which are left to FDA's discretion. 21 U.S.C. § 355(e)(5). As in *Chaney*, the language here "applies only to a situation where a violation has already been established to the satisfaction of the agency." *Chaney*, 407 U.S. at 837. Section 355(e) contains no discussion of whether and when FDA is required to initiate proceedings to withdraw approval of an NDA. *See Sierra Club*, 648 F.3d at 855. Thus, the same result should obtain in this case.

While § 701(a)(2) may be "rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers," *Chaney*, 470 U.S. at 833-34, Congress provided no such guidelines here. In its Complaint, Plaintiff references *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013), but the statutory provision at issue there included *explicit mandatory language in* both *an antecedent step* (*i.e.*, 21 U.S.C. § 381(a) provides that FDA "shall" obtain samples of imported drugs manufactured in unregistered facilities) and *the consequent* (*i.e.*, "[i]f it appears from the examination of *such samples* or otherwise" that the article is violative, then the article "shall be refused admission"). *See id.* at 7 (holding provision "sets forth precisely when the agency must determine whether a drug offered for import appears to violate the FDCA, and what the agency must do with such a drug."). There is no such language related to the investigatory step of the provision at issue here.

c. The Second Circuit's Analysis of Nearly Identical Statutory Language Confirms Congress Conferred Absolute Discretion on FDA to Initiate Withdrawal Proceedings

The Second Circuit applied the Supreme Court's analysis in *Chaney* to almost identical statutory language to reverse a district court's order that FDA "institute withdrawal proceedings." *See NRDC*, 760 F.3d at 157, 176 (reversing order compelling FDA to hold a hearing and remanding for dismissal of plaintiff's complaint). The FDCA provision at issue in *NRDC* set forth requirements for withdrawing approval of new animal drug applications and had the same structure and much of the same language as the provision at issue here. *Compare* 21 U.S.C. § 360b(e)(1) *with* § 355(e); *see also NRDC*, 760 F.3d at 180 (noting the two sections have the "same congressional design," "were once a single statutory section," "apply much the same process for the approval of drugs," and "use the same syntax in their respective withdrawal provisions"). Both sections state that "[t]he Secretary shall, after due notice and opportunity for hearing to the applicant," withdraw approval of an application if the Secretary makes certain findings.[10] *Id.* In other words, both sections provide conditions that if satisfied—an opportunity for hearing and then an adverse finding—would direct FDA to withdraw approval of an application. *Id.*

In *NRDC*, the principal question on appeal was whether the statute obligated FDA to proceed with a hearing to withdraw approval of applications for certain animal feed containing subtherapeutic levels of antibiotics. *Id.* at 157-58. Unlike here, FDA had already made public a determination that use of the feed was "not shown to be safe" for humans and had issued notices

[10] Section 360b(e)(1) states that the Secretary "shall . . . issue an order withdrawing approval," whereas § 355(e) omits "issue an order," and instead states that the Secretary "shall withdraw approval." This difference has no bearing on the operation of these two provisions.

of opportunity for hearings on the applications.[11] *Id.* Resolving the case required the Second Circuit to first determine the sequence of events specified in the statute. *Id.* The government argued that the statute first required a hearing, which could then lead to an adverse finding, and only after these two events, FDA "shall . . . issue an order withdrawing approval." *Id.* NRDC, however, interpreted the statute to require a "finding, hearing, finding, and order"—meaning that the statute used finding to mean both an "initial finding" that required FDA to publish a notice of opportunity for hearing, as well as a second finding "after the sponsor has been given notice and an opportunity to be heard" that, if adverse, required the issuance of an order of withdrawal. *Id.* at 159.

Ultimately, the Second Circuit found "the government's interpretation [to be] far more plausible, both as a matter of language and as a matter of conventional legal practice." *Id.* at 160. Part of maintaining "conventional legal practice," the court reasoned, included respecting FDA's enforcement discretion, which would be discarded under plaintiff's interpretation. *Id.* at 160, 171. Citing *Chaney*, the Second Circuit noted that, "the Supreme Court has long applied a presumption against judicial review of agency decisions declining to proceed with enforcement actions because such decisions are, for purposes of the . . . APA . . ., 'committed to agency discretion.'" *Id.* at 171 (citing *Chaney*, 470 U.S. at 832-33). The court then explained that if, as plaintiff argued, FDA's initial concerns automatically required a hearing, FDA would be stripped

[11] Here, Genus seeks a far more aggressive curtailing of FDA's discretion than that sought in *NRDC*. In *NRDC*, the plaintiff could point to initial FDA determinations about the safety of the animal feed and the publication of notices of opportunity for hearings to argue that FDA was compelled to hold hearings. *NRDC*, 760 F.3d at 156. And even then, the plaintiff requested FDA withdraw approval of the drugs only after the hearings and "*if appropriate*." *Id.* (emphasis added). Here, FDA has made no such initial determinations and it is unclear whether Genus is seeking an order compelling FDA to offer a hearing or immediately withdraw approval of Lannett's application. (Comp. ¶¶ 41, 42, 44, at 24.)

of its discretion to determine when a matter should proceed to a hearing. *Id.* After parsing the statute, the court was "firmly persuaded that Congress *has not* required the FDA to hold hearings whenever FDA officials have scientific concerns about the safety of animal drug usage." *Id.* (emphasis added).

The Second Circuit thus recognized, in accordance with *Chaney*, that "FDA *retains the discretion to institute or terminate proceedings* to withdraw approval of animal drugs by issuing or withdrawing [notices of opportunities for hearing]." *Id.* at 171-72 (emphasis added). The court explained that the statute only directs FDA action once the agency has made a finding *after* a hearing: "the statutory mandate contained in § 360b(e)(1) applies to limit the FDA's remedial discretion by requiring withdrawal of approval of animal drugs or particular uses of such drugs *only when the FDA has made a final determination, after notice and hearing*, that the drug could pose a threat to human health and safety." *Id.* (emphasis added). That plaintiff's interpretation of the statute denied FDA the discretion to "choose [its] own enforcement priorities" gave the Second Circuit reason to reject it. *Id.* at 171.

The Second Circuit's analysis of FDA's discretion with respect to a parallel section of the FDCA supports dismissal here. Considering nearly identical language, the Second Circuit concluded that the text of the statute and legal norms dictate that "FDA retains the discretion to institute or terminate proceedings to withdraw approval." *Id.* at 171-72. Only after notice, an opportunity for hearing, and an adverse finding does the statute direct FDA to withdraw approval of an application. *Id.* at 172.[12] There, as here, Congress committed to FDA absolute discretion

[12] *But see Am. Pub. Health Ass'n v. Veneman*, 349 F.Supp. 1311, 1315 (D.D.C. 1972) ("Thus it could not be clearer that the Secretary *must* begin the procedures to withdraw a drug [under 21 U.S.C. § 355(e)] when he concludes that there is no substantial evidence of efficacy." (emphasis in original)). While FDA believes its discretion extends beyond what is described in *Veneman*,

to determine whether and when to initiate proceedings to withdraw approval of a new drug application. *See* 5 U.S.C. § 701(a)(2). The Second Circuit rejected an interpretation of a similar FDCA provision that constrained FDA's discretion, *id.* at 171, and for the same reasons, this Court should reject that interpretation here.

In sum, Congress conferred absolute discretion to FDA in determining whether and when to investigate allegations of untruthful statements in applications, whether any such statements are material, and whether to institute subsequent proceedings to withdraw approval of applications. Such FDA decisions are unreviewable under 5 U.S.C. § 701(a)(2). Thus, the Court lacks subject matter jurisdiction and Genus's Complaint should therefore be dismissed.

2. The Administrative Procedure Act Precludes Judicial Review Where There is No Legally Required Agency Action

The APA provides another jurisdictional hurdle that Genus cannot overcome. Genus requests that this Court compel FDA to "immediately initiate proceedings to withdraw approval" of Lannett's application, but the Court can only compel actions that the agency is "legally required" to take. *See* 5 U.S.C. § 706(a); *see also Gonzalez v. Cuccinelli*, __ F.3d ___, No. 19-1435, 2021 WL 127196, at *5 (4th Cir. Jan. 14, 2021) ("[W]here an agency is *not required* to do something, we cannot compel the agency to act." (emphasis in original)); *City of New York v. U.S. Dep't of Def.*, 913 F.3d 423, 432 (4th Cir. 2019) (citing *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004)).

As the Fourth Circuit explained, "When a plaintiff brings a claim to compel agency action . . . [u]nder [§ 706(1) of] the APA, actions that can be compelled are only those that have been "unlawfully withheld or unreasonably delayed." *City of New York*, 913 F.3d at 432 (citing

FDA has not even made a public, preliminary determination about the veracity or materiality of the statements at issue in Lannett's application.

5 U.S.C. § 706(1)). When a party challenges an agency's failure to act, it *must* identify an action that the agency was "legally required" to take. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (explaining that "[t]his limitation appears in § 706(1)'s authorization for courts to 'compel agency action unlawfully withheld'" (quoting 5 U.S.C § 706(1))).

As explained above, FDA was not "legally required" under § 355(e) to take any action until and unless FDA published a notice of opportunity for a hearing and made an adverse finding. Section 355(e) reserves for FDA the discretion to investigate and then publish a notice of opportunity for hearing proposing to withdraw approval of an NDA. *See* 21 U.S.C. § 355(e). Because Genus can identify no action that FDA "unlawfully withheld," Genus requests relief that cannot be granted. Thus, for this additional reason, the Complaint should be dismissed.

B. Genus Lacks Standing

Even if Genus can clear the APA hurdles, the Complaint should still be dismissed because Genus lacks standing to bring this litigation.

Article III of the United States Constitution limits the jurisdiction of federal courts to actual "cases or controversies." U.S. Const. art. III, § 2. The standing doctrine is "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To establish Article III standing: (1) "the plaintiff must have suffered an 'injury in fact'"; (2) "there must be a causal connection between the injury and the conduct complained of"; and (3) "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Id.* at 560-61. "The party invoking federal jurisdiction bears the burden of establishing these elements." *Id.* at 561.

In addition to these requirements, the Supreme Court has set forth "a set of prudential principles that bear on the question of standing." *Bennett v. Spear*, 520 U.S. 154, 162 (1997). One of those principles requires a plaintiff challenging an agency action to demonstrate that it is

within the "zone of interests" protected or regulated by the statutory provision in question. *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 395-96 (1987).

Genus has failed to establish that it has standing to bring this litigation. Competitor standing is not conferred on Genus simply because Lannett and Genus compete. Genus must also have suffered a cognizable Article III injury, which it has not. In addition, Genus's requested relief is unlikely to redress its claimed injury because such redress depends on a speculative chain of events that may or may not occur. Genus also cannot invoke third-party standing with its brief reference to patient harm. Finally, Genus lacks prudential standing because it alleges only its own economic harm, which falls outside the "zone of interests" protected by the relevant provision of the FDCA. For all of these additional reasons, Genus's Complaint should be dismissed.

1. Genus Lacks Constitutional Standing

a. Genus Has Not Suffered an Injury Sufficient to Confer Article III Standing

According to its Complaint, Genus's injury stems from Lannett remaining as Genus's sole competitor in the market for cocaine-based anesthetic drug products based on FDA's failure to "withdraw [the] approval" of Lannett's NDA. (Compl. ¶ 65.) Specifically, Genus alleges that FDA's not having initiated withdrawal proceedings harms Genus financially, stating "Genus will suffer a loss of market share, resulting in significant financial harm," if FDA does not "withdraw Lannett's approval." (Compl. ¶ 65.) This injury is insufficient to establish standing.

The cause of Genus's alleged injury is FDA's "failure" to act—not with regard to Genus, but against Lannett. "When the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Lujan*, 504 U.S. at 562; *see also Linda R.S. v. Richard D.*, 410 U.S. 614, 619

(1973) ("[I]n American jurisprudence . . . a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.")

Because the alleged failure to act does not directly affect Genus, Genus can only demonstrate standing as a competitor in the same market, sometimes referred to as the "competitor standing doctrine." Under this doctrine, a plaintiff can demonstrate standing by showing "it is a direct and current competitor whose bottom line may be adversely affected by the challenged government action." *KERM, Inc. v. F.C.C.*, 353 F.3d 57, 60 (D.C. Cir. 2004).

Competitor standing is limited. As the Supreme Court has held, a market participant does not establish Article III injury "whenever a competitor benefits from something allegedly unlawful . . . . [W]e have never accepted such a boundless theory of standing." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 99 (2013). Rather, standing must be "based on an injury more particularized and more concrete than the mere assertion that something unlawful benefited the plaintiff's competitor." *Id.* Further, injury that is based on a "'chain of events' is too remote to confer standing." *New World Radio, Inc. v. F.C.C.*, 294 F.3d 164, 172 (D.C. Cir. 2002).

"The basic requirement common to all our [competitor standing doctrine] cases is that the complainant show an actual or imminent *increase in competition*, which increase we recognize will almost certainly cause an injury in fact." *Sherley v. Sebelius*, 610 F.3d 69, 73 (D.C. Cir. 2010) (emphasis added); *see also New World Radio*, 294 F.3d at 172 ("'[The C]ompetitor standing' doctrine [applies] to an agency action that itself imposes a competitive injury, i.e., that provides benefits to an existing competitor or expands the number of entrants in the petitioner's market, not an agency action that is, at most, the first step in the direction of future competition."). Plaintiffs are "afforded competitor standing when they assert[] a competitive injury as a result of an unlawful activity that was itself directly related to, and intended to

regulate, the commercial . . . marketplace." *Citizens for Responsibility and Ethics in Washington v. Trump,* 939 F.3d 131, 173 (2d Cir. 2019) (J. Walker, dissenting).

The brief discussion of the competitor standing doctrine in the Fourth Circuit underscores that the doctrine relates to specific agency action with immediate consequences to the market. *See Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 n.10 (4th Cir. 2000) (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998); *Schering Corp. v. FDA*, 51 F.3d 390, 395 (3d Cir. 1995); *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 11 (D.C. Cir. 1998). In *Zeneca*, the Fourth Circuit's citations and parenthetical descriptions explain that "competitor standing" requires an actual affirmative agency decision that directly increases competition: "a firm has constitutional standing to challenge a competitors' *entry* into its market"; "loss of monopoly profits *upon FDA approval* of a competitor generic substitute is sufficient to meet the Article III injury-in-fact standing requirement"; "*increased competition* represents a cognizable Article III injury." *See Zeneca,* at 170 n.10 (emphasis added).

The competitor standing doctrine does not encompass the market harm alleged in Genus's Complaint. Genus challenges FDA's inaction in not initiating proceedings to withdraw approval of Lannett's application. But Genus does not allege that FDA's exercise of discretion caused the entry of any competitor into the market, "lift[ed]" any "regulatory restriction," or otherwise caused an "*increase* in competition" for Genus. *Sherley*, 610 F.3d at 72 (emphasis added). FDA's discretionary action also does not "directly relate[] to . . . the commercial . . . marketplace." *Citizens for Responsibility and Ethics*, 939 F.3d at 173. Put simply, an agency's exercise of prosecutorial discretion to *not* act against a company does not result in any change in competition and, thus, does not support standing for the company's competitor. *Cf. KERM.*, 353

F.3d at 61 (holding plaintiff lacked competitor standing where plaintiff did not identify any lost revenues from FCC's decision to not take an enforcement action against a competitor).

Further, Genus's theoretical competitive harm is too speculative to satisfy the "competitor standing doctrine." "[T]he case law is clear that when the prospect and nature of future competition remains indeterminable and amorphous pending future clarifying events that postdate the filing of the complaint . . . the competitive injury requirement is not satisfied." *Delta Air Lines, Inc. v. Exp.-Imp. Bank of United States*, 85 F. Supp. 3d 250, 267 (D.D.C. 2015). Genus claims that, if FDA investigated Lannett, FDA would necessarily decide to withdraw Lannett's application. (Compl. ¶¶ 75,76.) However, as discussed more fully in the following section, even if the agency were ordered to investigate Lannett, there is no certainty that FDA would decide to withdraw approval of Lannett's application.

Finally, Genus alleges the potential harm of patients receiving "unsafe or ineffective drugs." (Compl. ¶ 64.) This injury is not "concrete and particularized," but rather "conjectural" and "hypothetical." *Lujan*, 504 U.S. at 560. Genus attempts to draw a nexus between Lannett's allegedly untrue statements and patients receiving "potentially unsafe or ineffective drugs," alleging that FDA was "deprived" of "the opportunity to conduct a . . . Numbrino®-focused pre-approval inspection of the facility in Carmel." (Compl. ¶ 68.) But the FDCA requires that facility changes be reviewed by FDA. 21 U.S.C. § 356a. And Genus fails to allege that an inspection was legally required as part of that review or that FDA was deprived of any other oversight that could call into doubt the safety and effectiveness of Lannett's drugs.

Because Genus lacks a cognizable direct injury Genus's Complaint should be dismissed.

b. Genus Cannot Demonstrate that its Requested Relief Will Likely Redress its Alleged Injury

Even if Genus could be considered to have suffered a direct injury, it is entirely "speculative" and not "likely" that the injury will be "redressed by a favorable decision," thus precluding standing. *Lujan*, 504 U.S. at 561 (quoting *Simon v. E. Kentucky Welfare Rts. Org.*, 426 U.S. 26, 41-42 (1976)).

Genus alleges its harm is directly related to competition from Lannett. (Compl. ¶ 64.) In its Complaint, Genus asks the Court to "[e]nter an order compelling FDA to immediately initiate proceedings to withdraw approval of Lannett's Numbrino® NDA." (*Id.* at 24.) But the multi-step withdrawal process set out in § 355(e) and further described in 21 C.F.R. § 314.200 requires several discretionary decisions by FDA. And, even if initiated, the process might not ultimately lead to the elimination of Lannett as Genus's sole competitor.

An FDA inquiry would first evaluate Lannett's statements about its intended manufacturing facility. 21 U.S.C. § 355(e). FDA would then have to find that the statements in the application are not only "untrue," but also "material." *Id.* Genus's Complaint assumes FDA can reasonably come to only one conclusion if it investigates, but that is not necessarily so. In *Genus I*, Genus's motion to vacate raised, for the first time in that case, the same allegations relating to Lannett's statements about its intended manufacturing facility, and Lannett filed a declaration in response. *See* Pl.'s Mot. to Vacate, *Genus Lifesciences, Inc. v. Azar*, Case No. 1:20-cv-211, ECF No. 66, at 8 (D.D.C. Oct. 16, 2020); Def.'s Mem. in Opp'n to Mot. for Recons. and Opp'n to Genus's Mot. for Vacatur, ECF No. 68-1 (D.D.C. Oct. 30, 2020) (attached as Ex. A). Lannett's declaration responds to Genus's allegations and shows the complexity of

evaluating the truth and materiality of Lannett's statements.[13] ECF No. 68-1 (D.D.C. October 30, 2020).

In particular, the declaration asserts that "the statements in the Genus brief are false" and that "no such misrepresentations were ever made to the FDA." *Id.* at 2. The declaration further avers that "[b]ased on discussions with the FDA, Lannett agreed to cease manufacturing its cocaine hydrochloride product" while "maintaining the site in a state of cGMP compliance and manufacturing readiness through approval of the NDA to support an FDA site prior approval inspection." *Id.* at 4. The declaration concludes, "Thus, contrary to the statements in the Genus Motion, there were no misrepresentations made by Lannett; rather, the pathway chosen by Lannett to ultimately transfer its manufacturing site for its Numbrino product was transparent, supported by FDA regulations, and approved by the FDA pursuant to well-established accepted procedures." *Id.* at 5. The declaration belies Genus's simplistic rendering of the statements about Lannett's manufacturing facility and shows it is no certainty that FDA would find Lannett's statements "untrue" and "material."

And even if FDA preliminarily determined Lannett's statement to be "untrue" and "material," FDA would not be obligated to publish a notice of opportunity for hearing. Under FDA's enforcement discretion, it can decide whether its limited resources are best spent on such a hearing. *NRDC*, 760 F.3d at 172 (holding, based on nearly identical statutory language, "we conclude that the decision whether to institute or terminate a hearing process that may lead to a

[13] Federal Defendants reference this declaration not to establish any specific facts, but to show that the issue is far more complex than Genus alleges and that FDA would not necessarily reach the result Genus seeks. FDA is not suggesting that it has made any determinations as to the validity or significance of these statements.

finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA.").

And even with a hearing, no particular result is preordained. A hearing would not necessarily lead to a finding that would result in withdrawing approval of Lannett's application—as Genus assumes. The purpose of the hearing would be to "determine whether the evidence does indeed show" that the statement is both "untrue" and "material." *Id*. at 160. In sum, the issue is far more complex than Genus's allegations portray, and the outcome, even if FDA were ordered to initiate proceedings, is far from certain. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013) ("[W]e have been reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment."); *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."); *Linda R.S.*, 410 U.S. at 618 (holding mother lacked standing to sue for an injunction requiring the district attorney to enforce a child support statute against the father because she failed to show her requested relief of child support payments resulted from the non-enforcement of the statute).

Because redressing Genus's alleged injury depends on a chain of events that is entirely speculative, Genus lacks standing.

2. Genus Lacks Third-Party Standing on Behalf of Patients

Genus also alleges that FDA's failure to initiate withdrawal proceedings will harm patients. (Compl. ¶¶ 64-69.) Specifically, Genus's Complaint alleges that FDA's exercise of its discretion "will endanger public health and safety by exposing Americans to a potentially unsafe or ineffective drug made in a facility about which Lannett provided materially false information in the CMC [Chemistry, Manufacturing, and Controls] section of its application." (*Id.* at ¶ 66.) This, in turn, allegedly deprived FDA of "the opportunity to review an accurate CMC section

and to decide, based on that information, whether to approve Lannett's application and whether to inspect the facility prior to approval to ensure that it could manufacture Numbrino® safely and properly." (*Id.*) But these allegations are insufficient to support a claim of third-party standing.

Generally, "a plaintiff must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975); *see also Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004). Although the Supreme Court has "recogniz[ed] that there may be circumstances where it is necessary to grant a third-party standing to assert the rights of another," *Kowalski*, 543 U.S. at 129, it has generally limited this exception by requiring parties seeking third-party standing to make two showings. First, the court must ascertain whether the party asserting the right has "a close relation[ship]" with the person who possesses the right. *Powers v. Ohio*, 499 U.S. 400, 411 (1991). Second, the court must consider whether there is a "hindrance" to the possessor's ability to protect his own interests. *Id.*

Neither of the requirements for third-party standing are satisfied here. As to the close-relationship requirement, there is no indication that Genus possesses a close relationship with the patients it seeks to protect. Indeed, it is by no means clear that Genus's interests are even remotely aligned with the interests of patients, who would likely suffer if Genus's sole competitor were to exit the market. Moreover, there is no reason to believe that patients would be unable to bring a lawsuit to protect their own interests.

Genus thus lacks standing to bring any third-party claim.

3. Genus Lacks Prudential Standing Because Its Alleged Injury is Not Within the Zone of Interests Protected by the Relevant FDCA Provision

Even if the Court finds that Genus has constitutional standing under Article III, Genus cannot demonstrate prudential standing. Genus alleges an injury to its market share.[14] (Compl. ¶ 65.) But this injury falls outside the "zone of interests" protected by § 355(e), which is directed at ensuring the continued safety and efficacy of approved drugs.

To establish prudential standing, a plaintiff challenging the action of a federal agency must demonstrate that the action is within the "zone of interests" protected or regulated by the statutory provision in question. *Clarke*, 479 U.S. at 395-96. Specifically, a plaintiff must demonstrate either: "(1) that it is an intended beneficiary of the statute that forms the basis of its claim, or (2) that it is a 'suitable challenger' to enforce the statute," in that the interests of the plaintiff are "sufficiently congruent with those of the intended beneficiaries that the litigants are not more likely to frustrate than to further . . . statutory objectives." *W. Wood Preservers Inst. v. McHugh*, 925 F. Supp. 2d 63, 73 (D.D.C.), *on reconsideration in part*, 292 F.R.D. 145 (D.D.C. 2013) (citing *Scheduled Airlines Traffic Offices, Inc. v. Dep't of Def.*, 87 F.3d 1356, 1359 (D.C. Cir. 1996) (internal quotation marks and citation omitted).)

Genus based its claim on the FDCA provision that authorizes the agency to withdraw approval of NDAs. But "[t]he [Federal] Food, Drug and Cosmetic Act was enacted and amended to protect *consumers* from impure, adulterated and dangerous food, drugs and medical devices." *Barnes v. Shalala*, 865 F. Supp. 550, 562 (W.D. Wis. 1994) (denying prudential

[14] Genus's "market share" is the sole harm at issue. While Genus's Complaint mentions "patient harm," Genus lacks standing to assert the rights of patients, for the reasons listed above. Also, Genus's assertion that safety concerns are raised by the manufacture of Lannett's drug in a facility other than the one identified in its NDA is unsupported by the allegations. The safety and effectiveness of Lannett's drug is unrelated to the truthfulness of the statements at issue in Lannett's application.

standing to farmers who sought to challenge FDA regulations that alleged only "predicted economic harm") (emphasis added). The FDCA is "not to protect manufacturers, producers or distributors against adverse economic consequences." *Id.*[15]

In a number of instances, the D.C. Circuit Court has declined to find prudential standing for plaintiffs attempting to harm rivals through APA litigation. For instance, in *Hazardous Waste Treatment Council v. EPA*, a trade association challenged EPA emission standards and "sought tighter controls on competitors." 861 F.2d 277, 285 (D.C. Cir. 1988). The D.C. Circuit rejected the trade association's standing argument, finding petitioner's interest was not in environmental purity, but in increasing the regulatory burden on its competitors. *Id.* To hold that this satisfied prudential standing, the D.C. Circuit stated, would be to create "a considerable potential for judicial intervention that would distort the regulatory process." *Id.* (internal quotations omitted); *see also Ass'n of Battery Recyclers, Inc. v. EPA*, 716 F.3d 667, 674 (D.C. Cir. 2013) (finding plaintiff lacked standing to challenge "EPA's failure to require that more stringent standards be imposed on the company's competitors" because "an industry group's interest in 'increasing the regulatory burden on others' falls outside the 'zone of interests' protected by the Clean Air Act."); *Cement Kiln Recycling Coal. v. EPA*, 255 F.3d 855, 870–71 (D.C. Cir. 2001) ("[T]he Council's interest lies only in increasing the regulatory burden on others. The Council therefore lacks prudential standing.") (citations omitted).

[15] There are some provisions of the FDCA, including subsections of 21 U.S.C. § 355, that are concerned with balancing the rights of competitors, who therefore fall within the "zone of interests." *See, e.g.*, *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006). But the proscription set out in § 355(e)(5) does not relate to competition and certainly was not intended to be used by a company seeking to remove its competitor from the marketplace.

Congress enacted this provision of the FDCA to protect consumers, not Genus's market share. As such, Genus lacks prudential standing because its harm falls outside the provision's zone of interests, thus providing another reason to dismiss Genus's Complaint.

C. Genus Failed to Exhaust Administrative Remedies

If the Court concludes that it has subject matter jurisdiction and that Genus has standing, the Court should still dismiss the Complaint because Genus failed to exhaust its administrative remedies before seeking judicial relief.

As the Fourth Circuit has explained, "It is a 'long-settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" *Cavalier Tel., LLC v. Virginia Elec. & Power Co.*, 303 F.3d 316, 322 (4th Cir. 2002) (citing *Myers v. Bethlehem Shipbldg. Corp.*, 303 U.S. 41, 50-51 (1938)). The APA also limits judicial review to "final agency actions." 5 U.S.C. § 704.

In its Complaint, Genus requests that the Court order the Commissioner of Food and Drugs to take an administrative action—to "immediately initiate proceedings to withdraw approval of Lannett's Numbrino® NDA." (Compl. at 24.) But, "[w]here relief is available from an administrative agency, the plaintiff is ordinarily required to pursue that avenue of redress before proceeding to the courts; and until that recourse is exhausted, suit is premature and must be dismissed." *Reiter v. Cooper*, 507 U.S. 258, 269 (1993).

FDA regulations require that any "request that the Commissioner take . . . any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a)," which details the citizen petition process. 21 C.F.R. § 10.45. When a plaintiff fails to file a citizen petition before requesting judicial relief, FDA regulations require the Commissioner to move for dismissal: "If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition

under § 10.25(a) [the citizen petition regulations]. . . *the Commissioner shall request dismissal* of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 *et seq.*, and the lack of an actual controversy as required by 28 U.S.C. 2201." *Id.* (emphasis added).

Genus's failure to submit a citizen petition requires dismissal of its Complaint. "Courts have often dismissed suits against the FDA for failure to utilize the citizen petition procedure." *Cody Labs, Inc. v. Sebelius,* 446 F. App'x. 964, 969 (10th Cir. 2011); *see also Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 358 F. App'x 179, 181 (D.C. Cir. 2009) (affirming dismissal when "[a]ppellants filed no such citizen petition with FDA . . . and they proffered no legally viable excuse for this failure"); *Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011) ("By failing to challenge the Warning Letters through a citizen petition, *see* 21 C.F.R. § 10.25, plaintiffs preclude, as a matter of law, judicial review of their claims."), *aff'd sub nom. Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012); *Garlic v. FDA*, 783 F. Supp. 4, 4 (D.D.C. 1992) (dismissing complaint because plaintiffs' had "not exhausted their administrative remedies by filing a 'citizen's petition' as required by 21 C.F.R. § 10.25(b)."); *cf. Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017) (affirming holding that plaintiff was required to file a citizen petition before pursuing court remedies, but reversing and vacating dismissal in favor of a stay).

While courts have discretion to decline to apply regulatory exhaustion in certain circumstances, no such special circumstances are present here. Courts will not require exhaustion where a plaintiff will be irreparably harmed by delay, the agency cannot grant effective relief, or exhaustion would be futile. *McCarthy v. Madigan*, 503 U.S. 140, 144-49

(1992). Here, Genus has not shown that any delay attendant to filing and waiting for a response to a citizen petition would irreparably harm the company. *See Cody Labs, Inc.*, 446 F. App'x at 970 ("[T]he only advantage Cody seeks is a slightly different regulatory burden. It is clear that Cody would not be unduly—or even significantly—prejudiced by following FDA regulations and filing a citizen petition."). Nor can Genus credibly argue that the filing of a citizen petition would be futile or that the agency could not grant effective relief. Indeed, the Court would never have to intervene if FDA were to grant such a petition. *See McKart v. United States*, 395 U.S. 185, 194 (1969) ("[F]requent and deliberate flouting of administrative processes could weaken the effectiveness of an agency by encouraging people to ignore its procedures.").

Beyond being required by regulations, one of the central reasons for the exhaustion doctrine noted by the Supreme Court is particularly apt here: "[j]udicial review may be hindered by the failure of the litigant to allow the agency to make a factual record, or to exercise its discretion or apply its expertise." *McKart*, 395 U.S. at 194. As noted above, Genus's allegations are far more complicated than they appear in the Complaint, and, if the Court were to review this matter (which it should not, for the reasons set out above), the focal point for its review would be the petition itself, related public comments, and the agency's response. 21 C.F.R. § 10.30(i). Without a response from the agency, the Court does not have the benefit of a considered agency decision to review. As the D.C. Circuit has cautioned, "the Court should not attempt to resolve these arguments before the FDA has the opportunity to apply its expertise and a record is developed." *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 23-24 (D.D.C. 2008), aff'd sub nom. *Ass'n of Am. Physicians v. FDA*, 358 F. App'x 179 (D.C. Cir. 2009). Genus can supply no reason to forego the exhaustion requirement here.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' Motion to Dismiss.

Dated: January 15, 2021

Respectfully submitted,

JENNIFER B. DICKEY
Acting Assistant Attorney General
Civil Division

DANIEL J. FEITH
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director

HILARY K. PERKINS
Assistant Director

/s/ Charles J. Biro
CHARLES J. BIRO
Trial Attorney
United States Department of Justice
Civil Division
450 5th Street, NW
Washington, DC 20001
Tel: (202) 307-0089
Email: Charles.Biro@usdoj.gov
Counsel for Federal Defendants

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on January 15, 2021, I electronically filed the foregoing document with the Clerk of the United States Court for the District of Maryland using CM/ECF.

Dated: January 15, 2021

/s/ Charles J. Biro
CHARLES J. BIRO